

**REMARKS**

**Introduction**

Claims 1, 2, 4, 5, 8, 9, 11, 12 and 22 are currently pending. Claim 22 has been allowed. The Examiner has withdrawn the Restriction Requirement as applied to claims 1, 2, 4, 5, 8, 9, 11-14 and 19.

Claims 1 and 8 have been amended to incorporate the elements of cancelled claims 2 and 9 and have been further amended as supported in the specification at page 10, lines 5-18. Furthermore, claims 1, 8 and 22 have been amended to correct typographical errors and claims 1, 5, 11 and 12 have been amended to correct antecedent basis. Claims 2, 9 and 13-21 have been cancelled without prejudice.

No new matter has been added.

**Claim Rejections Under 35 U.S.C. § 112, first paragraph**

Claims 1, 2, 3, 4, 5, 8, 9, 11-14, 19 and 20 were rejected under 35 U.S.C. § 112, first paragraph as allegedly containing subject matter not described in the specification in a way as to enable to make or use the invention and for allegedly lacking written description. Specifically, the Examiner asserts at pages 3-5 of the Office Action dated September 17, 2008, that the specification allegedly does not describe a step of separating unbound conjugate from the sample, the relationship of 6-keto-PGF<sub>1α</sub> antibodies to prostacyclin or prostaglandin levels, and what the terms “appropriate dose” and “therapeutic effect” mean. Applicant respectfully submits that the claim amendment and following comments obviate the rejections.

**Separating unbound conjugate from the sample**

The Examiner alleges on pages 3-4 of the Office Action dated September 17, 2008 that the specification does not provide sufficient written description for a method in which unbound

conjugate is separated from the sample. Applicants respectfully submit that claims 1 and 8 have been amended to obviate this rejection.

As now amended, claims 1 and 8 each recite, in pertinent part,

- (3) removing any unbound anti-6-keto-PGF<sub>1 $\alpha$</sub> -antibody and said conjugate following incubation;
- (4) measuring light intensity of the 6-keto-PGF<sub>1 $\alpha$</sub>  bound to the anti-immunoglobulin antibody.

This amendment is supported throughout the specification, for example on page 10, lines 5-18.

**Relationship of 6-keto-PGF<sub>1 $\alpha$</sub>  antibodies to prostacyclin or prostaglandin levels**

The Examiner at page 4 of the Office Action dated September 17, 2008 asserts that there would seem to be no correlation give, or easily discernible, for the relationship of 6-keto-PGF<sub>1 $\alpha$</sub>  to prostacyclin or prostaglandin level. Applicants respectfully disagree.

Applicants respectfully submit that the specification on page 1, lines 6-10, explains that the level of 6-keto-PGF<sub>1 $\alpha$</sub>  directly correlates to the level of prostacyclin in plasma. Moreover, the specification at page 3, lines 20-22 explains that 6-keto-PGF<sub>1 $\alpha$</sub>  is quantifiable and can be used as a surrogate marker for the level of plasma prostacyclin.

As such, it is clear that the amount of 6-keto-PGF<sub>1 $\alpha$</sub>  is directly correlated with the amount of prostacyclin in a sample and therefore a measurement of the amount of 6-keto-PGF<sub>1 $\alpha$</sub>  directly correlated to the amount of prostacyclin in the plasma sample.

Moreover, as explained in the specification at page 2, prostacyclin is a prostaglandin, and as such, 6-keto-PGF<sub>1 $\alpha$</sub>  can be used as a surrogate marker for the level of plasma prostaglandin.

**“Appropriate dose” and “therapeutic effect”**

The Examiner at pages 4-5 asserts that the terms “appropriate dose of prostacyclin” (claim 8) and “effect of a therapeutic agent” (claim 20) are not sufficiently described. As an initial matter, claim 20 has been cancelled without prejudice in an effort to expedite prosecution.

Furthermore, Applicant respectfully submit that the amendments to claim 8, which now recites, in pertinent part “[a] method of determining amount of prostaglandin in a plasma sample,” is supported by the specification at page 2 and page 3, lines 20-22, obviates the rejection.

Therefore, it is respectfully submitted that the claim amendments and the remarks obviate the rejections.

Accordingly it is respectfully submitted that the claims are allowable.

**Claim Rejections Under 35 U.S.C. § 112, second paragraph**

Claims 1, 2, 4, 5, 8, 9, 11-14, 19 and 20 were rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for failing to point out and distinctly claim the subject matter regarded as the invention.

Applicants respectfully submit that the claims amendments obviate these rejections and the claims are allowable.

In view of the above amendments and remarks, Applicants respectfully submit that this application should be allowed and the case passed to issue. If there are any questions regarding this Amendment or the application in general, a telephone call to the undersigned.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

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